Laboratory monitoring & evaluation tool Xpert Comprehensive Site Visit Assessment

This tool is intended to be used by staff/consultants undertaking laboratory monitoring and supervision visits on behalf of the National Tuberculosis Control Programme (NTP) to assess Xpert MTB/RIF test implementation. On-site supervisory visits form a critical part of the quality assurance programme associated with Xpert MTB/RIF implementation, and will be conducted at pre-determined time intervals as agreed by the NTP. Comprehensive site visit assessment will be conducted as an initial assessment of site competency after installation, and annually thereafter.

Name of Assessor(s)	
Title & organization of Assessor	
Name of laboratory being assessed	
Location of laboratory being assessed (City/Town, District and Country)	
Name and Contact details for person at laboratory	
Name of partner organization providing GeneXpert support	
What support does the partner organization supply?	
Date of last assessment / visit	
Reason for last assessment / visit	
Date of this assessment visit	

Xpert MTB/RIF test

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Section A: Laboratory & GeneXpert instrument information

General	
What kind of facility is this? ☐ Reference laboratory ☐ Regional or district laboratory ☐ Peripheral laboratory	Additional comments:
What tests are performed at this laboratory? ☐ TB tests ☐ Microbiology and / or serology ☐ Clinical chemistry ☐ Clinical hematology ☐ Cytology and / or histology ☐ Parasitology ☐ Other_____	Additional comments:
What TB tests are performed at this laboratory? ☐ GeneXpert Xpert MTB/RIF test ☐ Smear microcopy ☐ TB culture ☐ TB Drug susceptibility testing ☐ Line Probe Assay ☐ Other_____	Additional comments:

Staff and training	
How many staff are employed at this laboratory (including clerical staff and drivers)?	
How many staff are certified to perform the Xpert MTB/RIF test?	
Who conducted the Xpert MTB/RIF test training?	
How many days was the Xpert MTB/RIF training course?	
Has a follow-up Xpert MTB/RIF training course been conducted?	
How many staff are currently doing Xpert MTB/RIF testing?	

Xpert MTB/RIF test

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Referral & sample collection systems	
Are there satellite sites (clinics or hospitals) referring samples for Xpert MTB/RIF testing?	
If yes, how many satellite sites refer to this facility for Xpert MTB/RIF testing?	
Is there a sample transportation mechanism in place to send samples to this laboratory from satellite sites? If so, describe.	
How many kilometers to nearest satellite site?	
How frequently are TB samples collected from the satellite sites per week?	
Does the laboratory have refrigerator for storing sputum samples?	
Are any sputum samples for TB testing collected at this laboratory?	
If yes, is sputum collection done at a designated safe sputum collection booth/spot? Who supervisors sputum collection?	
Are suspects instructed how to produce good quality sputum?	
Are the patient details of samples found to be resistant to rifampicin communicated to a focal person (e.g. District TB Coordinator) within the TB programme?	
Are all samples with rifampicin resistant results sent for confirmation?	
Is there a sample transportation mechanism in place to send samples to a culture and DST laboratory?	

Infrastructure	
Does the laboratory have internet access?	
If yes, is internet access available in the TB laboratory?	
If yes, rate the consistency of the internet connection (0 – 7: where 0 is very inconsistent and 7 is highly consistent)?	
Is the laboratory connected to a generator?	
If yes, is fuel available for the generator?	
How long does the generator take to generate electricity?	
Rate the consistency of the power supply to the laboratory (0 – 7: where 0 is very inconsistent and 7 is highly consistent)?	

GeneXpert instrument & Xpert MTB/RIF test	
Is the computer attached to GeneXpert instrument a desktop or laptop computer?	
Is the latest software installed on the computer?	
How many modules does the GeneXpert instrument at this laboratory have?	
What is serial number of the GeneXpert instrument?	
What is the installation date of the GeneXpert instrument?	
When was the last calibration performed?	
When is the next calibration due?	
Are any modules currently malfunctioning?	
Are any modules currently being replaced?	
Have any repairs and / or troubleshooting been done since the last visit?	
Is the GeneXpert instrument connected to an uninterrupted power supply (UPS / inverter)?	
Is the computer attached to the GeneXpert instrument connected to an UPS?	
Has the laboratory provided uninterrupted testing services, with no disruptions due to equipment failure or stock-outs in the last year (or since the last assessment)?	
If no, what was the duration of the interruption and how was the matter resolved?	
Does the laboratory repeat Xpert MTB/RIF tests where an invalid result or error was obtained? Explain.	

Section B: Laboratory assessment checklist

1. Documents and records

		Yes	Partial	No	NA	Comment
1	Does the laboratory have the GeneXpert operator's manual and Xpert MTB/RIF instructions for use (hard or soft-copy)?					
2	Does the laboratory have a copy of the current national diagnostic algorithm?					
3	Are the following GeneXpert standard operating procedures available and read by all operators? a. GeneXpert operation					
	b. GeneXpert maintenance					
	c. Waste management					
	d. External quality assurance procedures					
	e. GeneXpert troubleshooting					
4	Are Xpert results archived on a regular basis?					
5	Is database back-up conducted on a regular basis?					

2. Organization and personnel

		Yes	Partial	No	NA	Comment
1	Is appropriate documentation available in GeneXpert instrument operators' personnel files (training certificates, competency assessment, health monitoring etc.)?					
2	Are meeting minutes available that show that operators of the GeneXpert instrument attend general laboratory staff meetings regularly and that issues related to Xpert MTB/RIF testing is discussed?					

3. Client Management and customer service

		Yes	Partial	No	NA	Comment
1	Are records in place documenting training that the laboratory has provided to clients (clinicians or Health Care Workers) regarding the Xpert MTB/RIF testing algorithm, sample type and results interpretation?					
2	Are records in place documenting notification to clients regards delays or interruptions in Xpert MTB/RIF testing (due to equipment failure, stock outs, staff levels, etc.)?					
3	Is there a tool for regularly evaluating client satisfaction and is the feedback received effectively utilized to improve services?					
4	Are clients correctly requesting Xpert testing according to the agreed algorithm?					

4. Equipment

		Yes	Partial	No	NA	Comment
1	Was the GeneXpert instrument verified on site prior to routine use as documented in the verification records?					
2	Was the GeneXpert instrument verified after servicing and repairs as documented in verification records?					
3	Is a root cause analysis conducted following equipment malfunction and are issues identified resolved by an adequate corrective action system?					

		Yes	Partial	No	NA	Comment
4	Is a system in place for ordering of calibration kits, servicing and instrument repairs?					
5	Are repair orders monitored to determine if the service has been completed?					
6	Are there back-up procedures for equipment failure (including SOPs for handling specimens during these times, identification of a back-up laboratory for testing, and referral procedures)?					
7	Are records in place documenting that maintenance/servicing needs are routinely communicated to upper management?					

5. Internal & external audits

		Yes	Partial	No	NA	Comment
1	Are records in place documenting that internal audits/assessments are regularly conducted?					
2	Are records in place documenting that recommendations for corrective/preventive actions have been developed and that there are clear timelines and ownership for follow-up?					
3	Are records in place documenting that external laboratory audits have been conducted?					
4	Are records in place documenting that reports from external audits have been communicated to laboratory management/GeneXpert instrument operators?					

6. Purchasing & inventory

		Yes	Partial	No	NA	Comment
1	Are all orders tracked until delivery and inspected, receipted, and labeled with date of receipt when the orders are checked in?					
2	Is an inventory control system in place that includes (acceptance and rejection of consumables, recording of lot number, date of receipt, received by and date placed into service; specifications for storage of consumables)?					
3	Are inventory records complete and accurate, with minimum and maximum stock levels denoted?					
4	Is the consumption rate monitored?					
5	Are stock counts routinely performed?					
6	Is First-Expiration-First-Out (FEFO) practiced?					
7	Are expired products labeled and disposed correctly?					
8	Does the laboratory have sufficient clean, dry and temperature-controlled storage space for Xpert MTB/RIF test cartridges (2-30°C)?					
9	Does the laboratory have enough regular supply of PPE (gloves, laboratory coats)?					

7. Process control

		Yes	Partial	No	NA	Comment
1	If specimens are not tested immediately, are they stored appropriately prior to testing?					
2	Are specimens and request forms of specimens submitted for Xpert testing adequately labeled/completed?					
3	Do the laboratory staff understand the algorithm? (question laboratory staff on key features of the algorithm to ascertain if they understand it)					
4	Did laboratory staff receive training in the diagnostic algorithm?					
5	If the laboratory processes more than one batch of samples at a time, is the maximum incubation time before loading into the cartridge less than 8 hours?					
6	Are specimens received from satellite sites packaged appropriately according to local and or international regulations?					
7	Are specimens transported to referral laboratories within acceptable timeframes (e.g. referral to NTRL for culture/DST)?					
8	Are referred specimens tracked properly using a logbook or tracking form?					
9	Does the laboratory participate in External Quality Assessment scheme (EQA) testing?					
10	Are the results of the two most recent EQA panels available in the laboratory?					
11	Were EQA results reviewed and feedback given to laboratory staff, and corrective actions taken for failed EQA?					
12	Does the laboratory staff check sputum samples for quality when received at the laboratory?					
13	Does the laboratory have an SOP and follow it on rejection of samples?					

8. Information management

		Yes	Partial	No	NA	Comment
1	Are testing personnel identified on the requisition and/or report?					
2	Are test results recorded in a logbook or electronic record in a timely manner?					
3	When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing?					
4	Are archived results (paper or data-storage media) properly labeled and stored in a secure location accessible only to authorized personnel?					
5	Is the record log filled completely and accurately, including a record of results received from other laboratories (e.g. NTRL)?					
6	Does the laboratory have a record of samples referred to NTRL for testing?					

9. Corrective action

		Yes	Partial	No	NA	Comment
1	Are Xpert errors recorded in a log?					
2	Are records in place documenting that appropriate action taken after any errors were reported, e.g. Record made, supervisor/mentor notified, repeat testing if possible?					

10. Document management						
		Yes	Partial	No	NA	Comment
1	Are quality indicators (TAT, rejected specimens, stock outs, number of tests performed etc.) recorded?					
2	Are records in place documenting that quality indicators are reviewed and used to improve laboratory performance?					

Section C: On-site procedural verification

1) Examine the GeneXpert instrument and Xpert MTB/RIF test workstation in the TB laboratory.

		Yes	Partial	No	NA	Comment
11. Facility and safety						
1	Is the size of the laboratory adequate and the layout of the laboratory, as a whole, organized so that the workstation is positioned for optimal workflow?					
2	Is each individual workstation maintained free of clutter and set up for efficient operation?					
3	Does the equipment placement/layout facilitate optimum workflow?					
4	Are all needed supplies present and easily accessible?					
5	Are the chairs/stools at the workstations appropriate for bench height and the testing operations being performed?					
6	Is 1:10 bleach solution made freshly on a daily basis?					
7	Is the GeneXpert instrument correctly placed and installed according to manufacturer's instructions?					

		Yes	Partial	No	NA	Comment
8	Is the GeneXpert instrument(s) uniquely labeled and marked?					
9	Is the GeneXpert instrument(s) asset number(s) recorded in an equipment logbook?					
10	Has the maintenance of the GeneXpert instrument being performed and documented at least on a daily/weekly/ monthly basis as appropriate?					
11	Is the laboratory climate-controlled for optimum GeneXpert instrument function?					
12	Is the maximum and minimum temperature in the laboratory recorded?					
13	Is the laboratory properly secured from unauthorized access with appropriate signage?					
14	Is the laboratory fridge(s) free of staff food items?					
15	Are patient samples stored in a separate fridge from reagents and blood products in the laboratory refrigerators and freezers?					
16	Is sufficient waste disposal available and is waste separated into infectious and non-infectious waste, with infectious waste autoclaved, incinerated, or buried?					
17	Is an appropriate fire extinguisher available, properly placed, in working condition, and routinely inspected?					
18	Is a spill kit available and complete?					
18	Is an operational fire warning system in place in laboratory with periodic fire drills?					
19	Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently?					
20	Are laboratory coats or gowns worn in the laboratory, but are not worn outside the work area?					

		Yes	Partial	No	NA	Comment
21	Are gloves and laboratory coats worn at appropriate times?					
22	Are drivers/couriers and cleaners working with the laboratory trained in biosafety practices relevant to their job tasks?					

2) Observe operators performing the Xpert MTB/RIF test (Note- this in an end-to-end evaluation i.e. from specimen processing to result reporting).

		Yes	Partial	No	NA	Comment
23	Did the operator organize the work area for the day's work?					
24	Did the operator add the correct volume of SR (sample reagent) to the sputum?					
25	Did the operator shake the sample, and mix twice before the end of incubation time?					
26	Was the incubation time 15 minutes (was a timer used)?					
27	Was the input volume transferred to the cartridge correctly?					
28	Did the operator start each new test in the GeneXpert instrument without any problem?					
29	Did the operator complete testing and dispose of cartridges appropriately?					
30	Did the operator seal the Xpert MTB/RIF reagents in a plastic bag before discarding?					
31	Did the operator dispose of all infectious materials (sputum cups, pipettes) properly (as per local guidelines for hazardous materials)?					
32	Did the operator clean the workbench with fresh 10% bleach before and after performing the Xpert MTB/RIF assay?					

		Yes	Partial	No	NA	Comment
33	Are operators able to easily retrieve primary test data on the instrument (e.g. for checking individual patient results, error codes etc.)					
34	Do all staff have their own passwords and are they used?					
35	Was the correct procedure followed for reporting of results?					

3) Check selected Xpert MTB/RIF test reagents to determine if all reagents in use (and in-stock) are currently within the manufacturer-assigned expiration dates.

		Yes	Partial	No	NA	Comment
36	Are all reagents in use (and in stock) currently within the manufacturer-assigned expiration dates?					
37	Are components of the kits mixed (i.e. SR buffer stored separately from cartridges)?					

4) Check 20 randomly selected Xpert MTB/RIF test request forms from the previous (one) month. Track the accuracy and completeness of data entry into each of the forms of documentation, namely request form, laboratory register and laboratory report form.

		Yes	Partial	No	NA	Comment
38	Were the patient and sample details correctly transcribed from the sample request form to the laboratory register?					
39	Were the results correctly transcribed from the Xpert MTB/RIF test report form to the laboratory report?					
40	Were the patient and sample details on the laboratory report form the same as the patient and sample details on the sample request form?					
41	Is the WHO reporting terminology used on the laboratory report?					

5) Check 20 randomly selected Xpert MTB/RIF test results from the previous (one) month. Record the average laboratory turnaround time (TAT) as determined by the difference between the sample receipt date & time and the date & time the Xpert MTB/RIF test was reported. Record the result below:

TAT
What is the average TAT for Xpert MTB/RIF test at this laboratory? ☐ < 4 hours ☐ 4 – 8 hours ☐ 8 – 12 hours ☐ >12 hours

Section D: Xpert MTB/RIF test data analysis summary

PERIOD_____(mmYYYY) to_____(mmYYYY)

GENEXPERT MTB/RIF TEST DATA **(Last three (3) months combined data for all instruments at the facility visited)**	Total
# Xpert tests MTB not detected	
# Xpert tests MTB detected RIF not detected	
# Xpert tests MTB detected RIF resistance detected (check that these cases are reported to RTLC)	
# Xpert tests MTB detected RIF indeterminate (check graphs for resistance patterns)	
# error results (more than 5% over 3 or more months report to focal point)	
# invalid results (more than 2% over 3 or more months report to focal point)	
# no result (more than 2% over 3 or more months report to focal point)	

Section E: Problem identification (complete if machine is not fully functional)

Identifying problems with GeneXpert	OK	Details of problem identified
Save a copy of the IQ report	☐	
Save a copy of the system log report (all)	☐	
Save a copy of last 3 months .gxx files	☐	

	If YES	Document problems identified
Is the machine, computer, UPS, cable visually damaged?	☐	
Do you have to open GeneXpert software manually?	☐	
Is each individual GeneXpert workstation cluttered and dirty?	☐	
Were there any critical errors (e.g. 1004, 1005, 2014) since the last assessment / visit?	☐	
Has regular maintenance been performed & recorded?	☐	
Are fan filters dirty?	☐	
Are cartridge bays dirty?	☐	

How many tests have been performed since the last plunger maintenance? ☐

How many cartridges are in stock? ☐

What are the expiry dates of the remaining stock? Date (dd/mm/yyyy)

Will stock run out or expire before next consignment? ☐

Section F: Non-conformances & corrective actions

Non-conformity	Recommended corrective action	Follow-up required

Conclusions:

Recommendations:

Signature of assessor: _____

Date: _____

Signature of recipient of report: _____

Designation (e.g. Site Manager, Clinician): _____

Date: _____